Complete Summary

GUIDELINE TITLE

Antiretroviral therapy.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Antiretroviral therapy. New York (NY): New York State Department of Health; 2004 Dec. 29 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Antiretroviral treatment of HIV infection. New York (NY): New York State Department of Health; 2003 Mar. 64 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Acquired immunodeficiency syndrome (AIDS)
- Adverse effects of antiretroviral therapy, including:
  - Bone marrow suppression
  - Pancreatitis
  - Lactic acidosis/hepatic steatosis
  - Hepatotoxicity
  - Renal toxicity
  - Myopathy/myositis

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Hematology
Infectious Diseases
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To develop guidelines for antiretroviral treatment of human immunodeficiency virus (HIV) infection

TARGET POPULATION

Human immunodeficiency virus (HIV)-infected patients

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Diagnosis

1. Viral load (plasma viral load)
2. Lymphocyte subsets (CD4 cell counts)
3. Human immunodeficiency virus (HIV) resistance assays
4. Antiretroviral serum levels (therapeutic drug monitoring) (not recommended)
5. Laboratory monitoring of antiretroviral therapy side effects
6. Monitoring for allergic reactions

Treatment/Management

1. Patient involvement in treatment initiation and planning, including:
    - Patient education and counseling on risks and benefits of therapy, measures to reduce HIV transmission, medication schedules, strict adherence, and side effects of therapy
    - Assessment of patient commitment to adherence to therapy
2. Selecting an initial antiretroviral regimen
    - For ARV-naïve patients, combination of two nucleoside reverse transcriptase inhibitors (NRTIs) (e.g., didanosine, lamivudine,

zidovudine, stavudine, tenofovir*, abacavir) plus either a protease inhibitor (e.g., amprenavir, nelfinavir, indinavir, ritonavir, lopinavir, saquinavir); or a non-nucleoside reverse transcriptase inhibitor (NNRTI) (e.g., nevirapine**)
        - For patients previously treated with only nucleoside analogs, observation and reevaluation of treatment guided by HIV resistance studies
3. Assessment and insurance of patient adherence to therapy
4. Changing a successful highly active antiretroviral therapy (HAART) regimen
    - Review of previous resistance testing
5. Second-line regimens and salvage HAART
    - Consultation with HIV specialist
    - Using a drug from a class not used in the first line regimen, using agents in novel antiretroviral (ARV) classes or with unique resistance profiles
6. Treatment for acute HIV infection
    - Laboratory testing including:
        - Quantitative HIV ribonucleic acid (RNA) or p24 antigen
        - Confirmatory HIV antibody testing
    - Patient education and counseling
7. Management of treatment interruption
    - Patient education about increased risk of transmitting HIV
    - Changing regimen before discontinuation
    - Continuing treatment for co-infections
8. Patient referral to research studies

*Note from the National Guideline Clearinghouse™: The U.S. Food and Drug Administration's (FDA) MedWatch Safety program distributed information from the manufacturer (Gilead Sciences, Inc) of tenofovir disoproxil fumarate (Viread®) about a high rate of early virologic failure and emergence of nucleoside reverse transcriptase inhibitor (NRTI) resistance associated mutations with the use of the drug in a once-daily triple NRTI regimen along with didanosine enteric coated beadlets (Videx EC, Bristol-Myers Squibb), and lamivudine (Epivir, GlaxoSmithKline). Based on these results, Tenofovir DF in combination with didanosine and lamivudine is not recommended when considering a new treatment regimen for therapy-naïve or experienced patients with HIV infection. Patients currently on this regimen should be considered for treatment modification. For more information, visit the FDA Web site.

**Note from the National Guideline Clearinghouse: On January 19, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine. The Indications and Usage section now recommends against starting nevirapine treatment in women with CD4+cell counts greater than 250 cells/mm3 unless benefits clearly outweigh risks. This recommendation is based on a higher observed risk of serious liver toxicity in patients with higher CD4 cell counts prior to initiation of therapy. See the FDA Web site for more information.

MAJOR OUTCOMES CONSIDERED

- Effectiveness of antiretroviral therapy in suppressing human immunodeficiency virus (HIV) replications, restoring and/or preserving immune function, reducing HIV-related morbidity and mortality, and improving quality of life
- Adverse effects of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including

infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person 3-4 times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Goals, Benefits, and Risks of Highly Active Antiretroviral Therapy (HAART)

Clinicians should prescribe a HAART regimen that is best able to delay disease progression, prolong survival, and maintain quality of life through maximal viral suppression.

Goals of Antiretroviral Therapy

- Maximal and durable suppression of viral replication (measured by viral load assays)
- Restoration and/or preservation of immune function
- Reduced human immunodeficiency virus (HIV)-related morbidity and mortality
- Improved quality of life

- Limitation of the likelihood of viral resistance to preserve future treatment options

The clinician should involve the patient in the decision-making process when deciding whether to implement antiretroviral (ARV) therapy. The clinician should review the benefits and risks of treatment for each individual patient. (See Table 2: Benefits and Risks of Antiretroviral Therapy in the original guideline document.)

Monitoring of Patients Receiving ARV Therapy

Monitoring Markers of HIV Infection

Viral Load

In ARV treatment-naïve patients or patients who are on a successful regimen, plasma viral load should be measured at baseline and every 3 to 4 months thereafter. Patients with CD4 counts >500 cells/mm^3 may require less frequent viral load monitoring.

Viral load should be measured immediately before initiation or change of ARV therapy and every 2 to 4 weeks after initiation or change until maximal suppression is documented. Once maximal suppression is attained, monitoring of viral load should take place every 3 to 4 months.

If there is a significant increase (3-fold increase or more) in viral load without clear explanation, measurement should be repeated to confirm virologic failure.

Virologic failure should prompt the clinician to assess the patient's adherence and to check for the presence of viral resistance.

Lymphocyte Subsets

Clinicians should measure CD4 cell counts at the time of diagnosis of HIV infection and every 3 to 4 months thereafter.

The absence of a significant CD4 cell count increase should not be interpreted as treatment failure if the viral load declines appropriately.

HIV Resistance Assays (See Table below)

Clinicians should perform genotypic resistance testing before initiating treatment in ARV therapy-naïve patients to determine whether they are infected with drug resistant virus.

Clinicians should perform resistance testing in cases of virologic failure or incomplete viral suppression.

When resistance testing is indicated, it optimally should be performed while patients are either receiving therapy or have been off therapy for less than 1 year.

Clinicians should consult with an expert to interpret the results of resistance assays because the results of resistance assays are often complex.

Table: Recommendations for the Use of Drug Resistance Assays

Clinical Setting/Recommendation	Rationale
Recommended	
Prior to initiating treatment in ARV-naïve patients, including in the setting of acute HIV infection	Determine if drug-resistant virus was acquired so that an appropriate regimen may be chosen.
Virologic failure during HAART	Determine the role of resistance in drug failure, and maximize the number of active drugs in the new regimen.
Suboptimal suppression of viral load after initiation of ARV therapy (In pregnant women initiating therapy, the clinician may not have as much time to monitor for suboptimal suppression.)	Determine the role of resistance, and maximize the number of active drugs in the new regimen if indicated.
Not generally recommended	
More than 1 year after discontinuation of drugs	Drug-resistance mutations may become minority species in the absence of selective drug pressure and may not be detectable. Current assays may not detect minority drug-resistant species.
Plasma viral load <500 to 1,000 HIV RNA copies/mL (The cutoff will vary according to the manufacturer of the kit.)	Resistance assays cannot be reliably performed because of the low copy number of HIV RNA.

Antiretroviral Serum Levels (Therapeutic Drug Monitoring)

Monitoring blood levels of ARV drugs is not currently recommended.

Laboratory Monitoring of Antiretroviral Therapy Side Effects

Bone Marrow Suppression

Complete blood counts should be measured before initiation of ARV therapy and every 3 to 4 months thereafter. For patients at high risk for bone marrow toxicity (e.g., those with advanced HIV infection, those with pre-treatment cytopenias, or

those who are receiving zidovudine or hydroxyurea), blood counts may have to be monitored more frequently because significant cytopenias may occur.

Pancreatitis

When patients receiving ARV therapy present with signs and symptoms suggestive of pancreatitis, clinicians should obtain serum amylase and lipase levels.

If signs or symptoms of pancreatitis occur in patients taking ARV medications, the clinician should temporarily suspend the entire ARV regimen. A new ARV regimen may be initiated when enzymes are normalized but should not include ARV medications that are most likely linked to pancreatitis.

An elevated serum amylase level should be confirmed with a serum lipase level.

Clinicians should not prescribe didanosine for patients who have a history of pancreatitis.

Lactic Acidosis/Hepatic Steatosis

When patients develop symptoms consistent with lactic acidosis syndrome in conjunction with an elevated lactate level (>2 mmol/L) and decreased serum bicarbonate (<20 mmol/L), the clinician should temporarily discontinue the entire ARV regimen while an evaluation is conducted.

Routine monitoring of serum lactate levels is not indicated in asymptomatic patients.

Patients who are asymptomatic and have an unexplained decrease in serum bicarbonate level (<20 mmol/L) should be promptly re-evaluated with a repeat test and a venous or arterial lactate. If the lactate is mildly elevated (2.1 to 5.0 mmol/L), the lactate should be repeated, an arterial blood gas should be obtained, and reassessment for the presence of symptoms associated with lactic acidosis should be performed. If the lactate is persistently elevated, the arterial pH is abnormal, or the patient has become symptomatic, ARV therapy should be discontinued.

Hepatotoxicity

Clinicians should obtain serum liver enzyme levels at baseline and every 3 to 4 months thereafter in patients receiving HAART.

Clinicians should screen for alcohol use in patients with abnormal serum liver enzyme levels.

Clinicians should not use full-dose ritonavir (600 mg twice daily) in patients with preexisting liver disease.

Clinicians should not use nevirapine* as part of the initial regimen in women with CD4 counts >250 cells/mm^3 or men with CD4 counts >400 cells/mm^3 because of an increased incidence of hepatotoxicity.

When initiating an ARV regimen that includes nevirapine*, clinicians should obtain serum liver enzymes at baseline, at the time of dose escalation, and 2 weeks after dose escalation.

Clinicians should counsel patients to seek medical evaluation when signs and symptoms of hepatitis, severe skin reactions, or hypersensitivity reactions related to nevirapine* occur. Serum liver enzymes should be obtained whenever patients develop a rash during nevirapine* therapy, particularly during the first 18 weeks of therapy

In the setting of hepatotoxicity related to nevirapine*, patients should not be rechallenged.

*See Note from the National Guideline Clearinghouse (NGC) regarding use of nevirapine at the end of the "Major Recommendations" field.

Renal Toxicity

Clinicians should measure serum creatinine levels at baseline and every 3 to 4 months thereafter in HIV-infected patients.

Myopathy/Myositis

Measurement of serum creatinine phosphokinase (CPK) is not routinely indicated. If the patient becomes symptomatic (e.g., muscle pain or weakness), CPK should be measured.

Monitoring for Allergic Reactions Associated with ARV Therapy

When patients receive any new ARV drugs, clinicians should educate them about the possibility of HAART-associated allergic reactions, including a hypersensitivity reaction, and the range of possible symptoms (refer to Table 5 in the original guideline document to view ARV drugs associated with allergic reactions).

Clinicians should discontinue offending drugs when there is a moderate to severe skin reaction, mucous membrane involvement, systemic toxicity, or fever.

Clinicians should avoid re-challenging patients with a medication that has been associated with a hypersensitivity reaction, especially in the setting of abacavir reactions and severe non-nucleotide reverse transcriptase inhibitor (NNRTI) reactions.

In patients who develop mild rash in response to nevirapine*, clinicians should avoid escalating the nevirapine* dose to twice daily until after the rash has resolved. For patients with moderate to severe cutaneous toxicity, nevirapine* should be discontinued and should not be re-challenged. Use of an alternate NNRTI should be avoided.

*See Note from the National Guideline Clearinghouse (NGC) regarding use of nevirapine at the end of the "Major Recommendations" field.

Initiating ARV Therapy

Patients should be involved in planning the treatment regimen and should make the final decision of when to initiate ARV therapy after counseling has taken place regarding specific issues relevant to his/her own clinical situation.

Initiation of HAART is recommended when:

- Patient-related barriers to adherence are minimized.
- Patient is symptomatic from HIV.
- CD4 counts are <350 cells/mm^3 (see Section IV in the original guideline document).
- Other acquired immune deficiency syndrome (AIDS)-defining condition is present.

The clinician should encourage strict safe-sex practices and avoidance of needle-sharing activity for all patients, regardless of viral load, to prevent HIV transmission or superinfection.

Clinicians should thoroughly counsel patients starting ARV therapy concerning the need for strict adherence and the risk of viral drug resistance when adherence is compromised (see "The Importance of Patient Adherence" section below). Adherence should be reinforced at regular intervals during the course of therapy.

The decision to begin ARV therapy should be individualized, made in the context of careful patient counseling and education, and based on an assessment of four major factors:

- The patient's risk of progression to illness or death if left untreated (see Figure 1 in the original guideline document)
- The patient's willingness to adhere to the therapy prescribed
- The presence of adherence obstacles
- The risk of long-term toxicity

The Importance of Patient Adherence

A team approach to achieving adherence should be used. Nurses, pharmacists, peer counselors, caseworkers, and others who work in outreach, evaluation, and support of adherence should be involved.

The clinician should assess treatment readiness prior to initiation of treatment, adherence readiness for subsequent regimens, and adherence at every clinical visit.

Interventions should be intensified in times of decreased adherence.

Information about patients' beliefs and attitudes should be communicated with all members of the healthcare team so that each practitioner can consistently

address treatment adherence issues within the context of the overall treatment plan.

If the patient is not fully committed to adhering to therapy, treatment should be delayed, and the clinician should continue to work on abating the patient's concerns. Appropriate referrals should be provided for support groups, mental health, and drug treatment.

Selecting an Initial Antiretroviral Regimen

For ARV therapy-naïve patients, the initial HAART regimen should include a combination of two nucleoside reverse transcriptase inhibitors (NRTIs) plus either a protease inhibitor (PI), or an NNRTI.

The goal of initial HAART in the ARV therapy-naïve patient should be to devise a regimen that will achieve maximal durable viral suppression (<50 copies/mL) and be tolerated for an indefinite period of time.

Clinicians should involve their patients when deciding which HAART regimen is most likely to result in adherence.

Clinicians should not use nevirapine* as part of the initial regimen in women with CD4 counts >250 cells/mm^3 or men with CD4 counts >400 cells/mm^3 because of an increased incidence of hepatotoxicity.

For women considering pregnancy or likely to become pregnant, efavirenz should be avoided. If there are no alternatives for efavirenz in women of childbearing age, the clinician should strongly advise the use of effective contraception.

Refer to Table 9 in the original guideline document for Recommended Antiretroviral Regimens for Initial Treatment of HIV Infection. Table 10 in the original guideline document lists possible dose combinations for protease inhibitors.

*See Note from the National Guideline Clearinghouse (NGC) regarding use of nevirapine at the end of the "Major Recommendations" field.

Choosing an Initial HAART Regimen for Patients Previously Treated with Only Nucleoside Analogs

Patients who have been maintained on mono, dual, or triple nucleoside regimens and who have significant viral suppression and a relatively intact immune system may be observed without switching therapy.

Choice of HAART regimens in nucleoside-experienced patients with suboptimal response should be guided by results of HIV resistance studies.

Changing a Successful Initial HAART Regimen

Clinicians should change a successful initial HAART regimen when the patient's adherence will be compromised by continuing the current regimen.

When considering a change in the ARV regime due to drug toxicity, it is important to confirm that the viral load is maximally suppressed. If maximal viral suppression has been achieved, the clinician should substitute the offending drug.

The clinician should review results from previous resistance testing before changing a successful regimen.

Failure to Achieve Goals of Initial HAART

Clinicians should address adherence, obtain resistance assays, and consult with an HIV Specialist before changing HAART regimens that have failed.

Clinicians should not change an ARV regimen when there is incomplete but significant viral suppression ($\geq$0.5 log reduction, or 3-fold, from baseline viral load value) compared with baseline and a more effective HAART regimen cannot be constructed as a result of drug resistance or intolerance.

Second-Line Regimen and Salvage HAART

Clinicians should consult with an HIV Specialist when constructing a second-line regimen and salvage therapy regimens.

Clinicians should review individual ARV history and results from HIV drug resistance testing when constructing salvage therapy regimens. Clinicians should consult with an expert to interpret the results of resistance assays.

Clinicians should use a drug from a class that was not used in the first regimen when constructing a second-line regimen.

When treating patients with high levels of HIV drug resistance, clinicians should consider using agents in novel ARV classes or with unique resistance profiles, such as the entry inhibitors or drugs available through clinical trials or expanded access.

Treatment of Acute HIV Infection

Clinicians should maintain a high level of suspicion for acute HIV infection in all patients presenting with a compatible clinical syndrome (see Table 11 in the original guideline document) and should immediately obtain appropriate laboratory testing (quantitative HIV ribonucleic acid [RNA] or p24 antigen).

Confirmatory HIV antibody testing should be performed 3 to 6 weeks after diagnosis by HIV RNA testing.

The potential benefits of therapy should be weighed against the potential risks, and the clinician and the patient should be aware that therapy of primary HIV infection is of unproven efficacy.

The clinician should counsel the patient regarding potential limitations of HAART in acute primary infection, and individual decisions should be made only after

weighing the risks and sequelae of therapy against the theoretical benefit of treatment.

Once the clinician and patient have made the decision to use ARV therapy for primary HIV infection, treatment should be implemented with the goal of suppressing plasma HIV RNA levels to below detectable levels.

Management of Treatment Interruption

Patients should be discouraged from stopping HAART without first consulting with their clinician. When HAART is interrupted, clinicians should educate patients about the potential increased risk of transmitting HIV. Risk-reduction counseling and prevention interventions should be intensified at this time.

When medically necessary to interrupt HAART in patients receiving ARV medications with prolonged half-lives, such as NNRTIs, clinicians should consider changing the regimen before discontinuation to avoid the emergence of resistance.

Because of potential exacerbations of hepatitis B, clinicians should not interrupt lamivudine, emtricitabine, or tenofovir** (or combination pills containing these drugs) in patients who are co-infected with chronic hepatitis B without implementing another treatment option.

Strategic treatment interruption (STI) is an experimental treatment approach and thus cannot be recommended outside of a research setting in the current management of the HIV-infected patient. To locate a clinical trial, refer to the AIDS Community Research Initiative of America clinical trials directory at http://www.criany.org/clinical_trials/

Referring Patients to Research Studies

Referral of patients to research protocols should be 1) to provide treatment or diagnostic options that may be otherwise unavailable and that may enhance treatment outcome, and 2) to attempt to answer a relevant research question.

Patients should be fully informed of any financial benefit their referral to a research study might have for the referring clinician.

Patients should be informed that research studies often require major commitments of time and effort in addition to potential unforeseeable risk.

The clinician should provide assistance to patients who want to participate in research studies.

*Note from the National Guideline Clearinghouse: On January 19, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine. The Indications and Usage section now recommends against starting nevirapine treatment in women with CD4+cell counts greater than 250 cells/mm3 unless

benefits clearly outweigh risks. This recommendation is based on a higher observed risk of serious liver toxicity in patients with higher CD4 cell counts prior to initiation of therapy. See the FDA Web site for more information.

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Antiretroviral Therapy

- The preservation and/or restoration of immune function
- Improvement of overall health and the prolongation of life
- The suppression of viral replication
- The possible decrease in risk of viral transmission to others (including fetal transmission)

Early Therapy

- Control of viral replication is easier to achieve and maintain
- Delay or prevention of immune system compromise
- Lower risk of resistance with complete viral suppression
- Possible decreased risk of HIV transmission

Delayed Therapy

- Minimization of negative effects on quality of life

- Avoidance of drug-related adverse events
- Delayed development of drug resistance
- Preservation of maximum number of available and future drug options until risk of human immunodeficiency virus (HIV) disease progression is higher

Individuals Most Likely to Benefit

Patients with advanced or rapidly progressive disease may be expected to gain the most from antiretroviral (ARV) therapy because they will experience a relatively greater increase in immune function and corresponding decrease in viral load.

POTENTIAL HARMS

Antiretroviral Therapy

- Adverse effects of the medications on quality of life (for adverse effects and drug interactions of specific antiretroviral drugs, see tables in appendices A-C of the original guideline)
- Known, and as yet unknown, long-term drug toxicities, including potential fetal toxicity
- The development of human immunodeficiency virus (HIV) drug resistance to drugs currently available and possibly to those not yet available, which may limit future treatment options

Early Therapy

- Drug-related reduction in quality of life
- Greater cumulative drug-related adverse events
- Earlier development of drug resistance if viral suppression is suboptimal
- Limitation in future ARV treatment options

Delayed Therapy

- Possible risk of further or irreversible immune system depletion
- Possible greater difficulty in suppressing viral load
- Potential increased risk of HIV transmission

CONTRAINDICATIONS

CONTRAINDICATIONS

See the appendices of the original guideline document for contraindicated combinations of antiretroviral drugs and other medications.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines do not offer an exact recipe for treating human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) because there is no one right way to treat HIV. Like all practice guidelines, the guidelines provide information and advice to assist doctors and patients in making treatment decisions. One single approach doesn't fit each person. The guidelines can help doctors and patients decide what kind of approach may work best in each individual situation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (HIV clinical practice guidelines, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience
- Define target audience (providers, consumers, support service providers).
    - Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)?
- Define implementation methods.
    - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes.
    - What steps need to be taken to make these activities happen?
    - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?
    - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
    - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor progress.
    - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate.
    - Did the processes and strategies work?
    - Were the guidelines implemented?
    - What could be improved in future endeavors?

IMPLEMENTATION TOOLS

Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Antiretroviral therapy. New York (NY): New York State Department of Health; 2004 Dec. 29 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Mar (revised 2004 Dec)

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Medical Care Criteria Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Chair: Amneris Luque, MD, Associate Professor of Medicine, University of Rochester Medical Center, Rochester, NY; Medical Director, AIDS Center, Strong Memorial Hospital

Vice Committee Chair: Sheldon Brown, MD, Liaison, Department of Veterans Affairs Medical Center; Associate Professor of Medicine, Mount Sinai School of Medicine, New York, NY; Chief, Infectious Disease Section, Bronx Veteran Affairs Medical Center (111F)

Committee Members: Bruce Agins, MD, MPH, Assistant Professor of Medicine, Cornell University Medical College, New York, NY; Medical Director, AIDS Institute, New York State Department of Health; Doug Fish, MD, Head, Division of HIV Medicine, Assistant Professor of Medicine, Albany Medical College; Charles Gonzalez, MD, Assistant Professor of Medicine, New York University School of Medicine, New York, NY; Clinical Investigator, AIDS Clinical Trials Unit, New York University Medical Center - Bellevue Hospital Center; Harold Horowitz, MD, Professor of Medicine, New York Medical College, Valhalla, NY 10595-1696; Medical Director, AIDS Care Center, Division of Infectious Diseases, Westchester Medical Center; Marc Johnson, MD, Attending Physician, New York Hospital Queens, Flushing, NY; Assistant Professor of Medicine, Mount Sinai School of Medicine, New York, NY; Medical Director, New York Hospital Queens Primary Care at ACQC; Jessica Justman, MD, Associate Professor of Clinical Medicine, Albert Einstein College of Medicine, Bronx, New York; Associate Director, Center for Infectious Disease Epidemiologic Research, Mailman School of Public Health, Columbia University; Sharon Mannheimer, MD, Assistant Professor of Clinical Medicine, Columbia University College of Physicians and Surgeons, New York, New York; Division of Infectious Diseases, Harlem Hospital Center; Neal Rzepkowski, M.D., HIV Care Consultant, New York State Department of Corrections, WENDE HUB; HIV Care Provider, Erie County Medical Center Rural Outreach Clinics, Chautouquez County Department of Health HIV Clinics; Kent Sepkowitz, MD, Memorial Sloan-Kettering Cancer Center; Rona Vail, M.D., HIV Clinical Director, Callen-Lorde Community Health Center; Barry Zingman, MD, Medical Director, AIDS Center, Montefiore Medical Center

Liaisons: Barbara Chaffee, MD, MPH; Joseph R. Masci, MD; Noemi Nagy

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Antiretroviral treatment of HIV infection. New York (NY): New York State Department of Health; 2003 Mar. 64 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Antiretroviral therapy. Tables and recommendations. New York (NY): New York State Department of Health; 2004 Jun. 49 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.
- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was prepared by ECRI on January 21, 2004. This NGC summary was updated by ECRI on February 8, 2005.

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